REMARKS

Applicants have amended the specification by adding sequence identifiers on page 18, line 13 of the specification and Figure 2 of the drawings as required under 37 C.F.R. §1.821-§1.825. Support for SEQ ID NO's may be found in the Sequence Listing submitted on June 13, 2002.

Applicants have amended the specification on page 18, line 16 to correct an obvious typographical error. The phrase on this line discussing flanking regions, ". . . residues at the – and C- terminus" should read ". . . residues at the N- and C- terminus." Support for this amendment can be found on Figure 5.

Applicants have amended claims 1, 10 and 11 to respond to the Examiner's rejections. Specifically, applicants have replaced the term "peptide mimic" in claims 1 and 11 with "isolated peptide mimic" according to the Examiner's suggestion. Support for these amendments is found on, *e.g.*, page 18, lines 13-22. Applicants have also amended claim 10 to more clearly recite "LOS" as "lipooligosaccharide" according to the Examiner's suggestion. Support for this amendment is found on, *e.g.*, page 3, line 2.

The above amendments to the specification and claims do not narrow the claims in any way. No new matter has been added.

The Objections

6) Regarding the objections to the drawings set forth in Form PTO 948, applicants will submit formal drawings upon receipt of the Notice of Allowability, as set forth in 37 C.F.R. § 1.85.

8(a) The Examiner has objected to the specification as not containing information about the priority claims of the present application to the provisional application filed on October 29, 1999.

Applicants have amended page 1 of the specification to add a paragraph claiming priority to the provisional application, thereby obviating the Examiner's objection.

8(b) The Examiner has objected to the specification because the amino acid sequence recited in line 13 on page 18 and those recited in Figure 2 are not identified by SEQ ID NO.'s as required under 37 C.F.R. § 1.821 through § 1.825.

Applicants have amended the specification at page 18, line 13 to include the SEQ ID NO., as requested by the Examiner. Applicants have also amended Figure 2 to include the SEQ ID NO.'s next to the recited amino acid sequences. Applicants believe that these amendments obviate the Examiner's objection.

8(c) The Examiner has objected to the specification, asserting that the recitation of "Figure 8 shows" on page 9, under "Brief Description of the Drawings" should be replaced with "Figure 8A-8D show."

Applicants have amended the specification accordingly. In addition to the instance at page 9, applicants have similarly amended page 21, line 23 to page 23, line 3 to reflect the same amendment. Applicants believe that these amendments obviate the Examiner's objection.

8(d) The Examiner has objected to the specification as incorrectly denoting trademarked items.

Applicants have amended the specification on page 9, lines 13-20 to recite the trademark CELLQUEST™ in capital letters and generic terminology, as suggested by the Examiner. Applicants have also amended the specification on page 18, line 31 to page 19 line 14 and page 20, line 23 to page 21, line 10 to recite the trademark TWEEN-20™ in capital letters and generic terminology "Polysorbate-20," as suggested by the Examiner. Applicants believe that these amendments obviate the Examiner's objection.

The Rejections

Double Patenting

The Examiner has rejected claims 1, 3 and 9-15 as being unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 1-3 and 6 of United States patent 5,476,784 (hereinafter "'784 patent"), claims 1-9 and 11 of United States patent 5,939,067 (hereinafter "'067 patent"), and claims 1-4 of United States patent 6,099,839 (hereinafter "'839 patent"). Specifically, the Examiner states that:

> claims 1-3 and 6 of the '784 patent, claims 1-9 and 11 of '067 patent , and claims 1-4 of the '839 patent recite or encompass the binding fragment of an anti-idiotypic monoclonal antibody or the antibody itself and/or a composition comprising an immunoprophylactically effective amount of the same, which immunospecifically binds to the idiotype of a second antibody which binds to an oligosaccharide epitope of *N. gonorrhoeae* which epitope is not present in human blood group antigens, wherein the oligosaccharide epitope specifically binds to monoclonal antibody 2C7 produced by a hybridoma cell line having the characteristics of HB 11311 as deposited with the ATCC.

Applicants traverse.

The '784, '067 and '839 patents disclose anti-idiotypic antibodies and fragments thereof useful in methods and compositions for the prevention and treatment of

N. gonorrhoeae infections. The instant invention, in contrast, teaches novel immunogenic peptides that mimic conserved gonococcal epitopes, and their use in the prevention and treatment of gonococcal infection. These peptide mimics are not fragments of anti-idiotypic antibodies. Applicants disagree with the Examiner's assertion that the discussion of binding fragments in the '784, '067 and '839 patents render obvious the peptide mimics of the instant invention. As discussed below, the anti-idiotypic fragments of the '784, '067 and '839 patents are not the same as the instant peptide mimics.

The '784, '067 and '839 patents nowhere teach or suggest the peptide mimics specified in the instant invention nor do they refer to the use of any peptide mimics in the treatment of *N. gonorrhoeae* infection. Although the term "fragments" is used in the '784, '067 and '839 patents, the term is defined as Fab fragments, Fab' fragments, $F(ab')_2$ fragments, F(v), fragments comprised of one or more complementarity determining region(s) (CDR), heavy chain monomers or dimers, light chain monomers or dimers, dimers consisting of one heavy and one light chain, and the like. See, *e.g.*, column 5, lines 30-37 of the specification of the '784 patent. One of ordinary skill in the art would know that these fragments typically contain more than 50 amino acid residues.

In contrast, applicants have defined the peptide mimics of their invention as a linear or cyclic chain of amino acids, usually at least 4 and less than 50 amino acids in length, which exhibits an immunological antibody binding profile similar to that of a known epitope (See specification, e.g., page 12, lines 1-6). These are not fragments of anti-idiotypic antibodies. The '784, '067 and '839 patents do not discuss peptide mimics at all. Therefore, applicants assert that the fragments of the '784, '067 and '839 patents

do not encompass any specific peptides of the instant invention, and would not render such peptide mimics obvious.

Moreover, the amino acid sequence of the peptides claimed in the instant invention has no similarity with any anti-idiotype fragment or subunit disclosed in the '784, '067 and '839 patents. To support this assertion, applicants submit a Declaration Of Peter A. Rice Under 37 C.F.R. § 1.132 ("Rice Declaration") showing that the amino acid sequence of PEP1 (See Figure 1), one of the peptides disclosed in the instant invention, has no significant similarity with the heavy chain (CA1 VH) or light chain (CA1 LH) subunit of the anti-idiotype antibody (mAb 2C7) disclosed in the '784, '067 and '839 patents (Rice Declaration ¶¶ 9-12). The sequence of PEP1 and the antibody subunits were aligned using the BLAST sequence alignment engine (www.ncbi.nlm.nih.gov).

Further, the anti-idiotypic antibody fragments of the '784, '067 and '839 patents do not convey to one of skill in the art a reasonable expectation of success in using the instantly claimed peptide mimics. There is no teaching in the '784, '067 and '839 patents of how to make the instantly claimed peptide mimics.

Applicants outline below a number of differences in the characteristics of the instantly claimed peptide mimics as compared to anti-idiotypic antibodies and fragments thereof taught in the '784, '067 and '839 patents.

First, the peptide mimics claimed in the instant invention were generated by selecting for immunogenic peptides from a library of random peptides (See specification at page 12, line 28 through page 13, line 8). These peptides are not derived from the anti-idiotypic antibodies of the '784, '067 and '839 patents. Second, the

chemical composition and purity of the synthesized peptides can be precisely defined and reproduced, since they involve only a small number of amino acid residues as compared to anti-idiotypic antibody fragments, which are typically much longer amino acid sequences. Third, the immunogenicity of peptide mimics can be significantly enhanced by polymerization or addition of relatively small carrier molecules that reduce the total amount of antigen required for immunization. This approach serves to "configurationally fix" the epitope creating a high density of peptides for enhanced immunogenicity. This is not discussed anywhere in the '784, '067 and '839 patents. Fourth, peptide mimics may be more practical than the production of anti-idiotope fragments simply because they are easier to produce in large-scale amounts and require minimal subsequent processing. Fifth, peptide mimic-based vaccines are generally free from contamination and are stable at ambient temperatures, thus eliminating the need for safeguards in preserving the peptides during the time period between manufacture and administration, unlike fragments of anti-idiotypic antibodies. Sixth, the stability of peptide mimics makes them suitable for application in delayed release vehicles. And finally, peptide mimics may involve fewer adverse effects than anti-idiotope preparations, such as unwanted production of rheumatoid factors and/or antigen-antibody complexes following immunization. There is thus a clear distinction in the subject matter of the instant invention and the subject matter of the '784, '067 and '839 patents, and a showing of improved efficacy with the instant peptide mimics.

For the above reasons, applicants believe that claims 1, 3 and 9-15 are non-obvious over claims 1-3 and 6 of the '784 patent, claims 1-9 and 11 of the '067

patent, and claims 1-4 of the '839 patent. Applicants respectfully request that the Examiner withdraw the double patenting rejection.

35 U.S.C. § 101

The Examiner has rejected claims 1 and 11 and the dependent claims therefrom under 35 U.S.C. §101 as being directed to non-statutory subject matter. Specifically, the Examiner asserts that the claims read on a product of nature, *i.e.*, naturally occurring peptide mimics. The Examiner contends that claims 1 and 11 lack limitations which distinguish the product from those that may exist naturally. The Examiner suggests that applicants amend the claims to recite "isolated peptide mimic" instead of "peptide mimics" to reflect the hands of the inventors in the production or creation of the recited product. Applicants traverse.

Applicant believes that as of the filing date of the application, peptide mimics would have been understood by one of skill in the art to comprise an isolated peptide. In the interest of expediting prosecution, however, applicants have amended claims 1 and 11 according to the Examiner's suggestion by replacing "peptide mimics" with "isolated peptide mimics" thereby overcoming the Examiner's rejection. These amendments do not narrow the claims in any way.

35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 2, 4-10 and 13-15 under 35 U.S.C. §112, second paragraph as being indefinite, for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The specific rejections under 35 U.S.C. §112, second paragraph are discussed below.

(a) The Examiner asserts that claim 10 is vague and indefinite in the abbreviated recitation "LOS," because it is unclear what is encompassed in this abbreviation. The Examiner suggests that applicants use the full terminology at first occurrence while retaining the abbreviation within parentheses.

Applicants have amended claim 10 according to the Examiner's suggestion. Specifically, applicants recite in claim 10 the full terminology of "LOS" and retain the abbreviation in parentheses thereby overcoming the Examiner's rejection.

(b) The Examiner states that claim 13 is vague and indefinite in the recitation "the characteristics of HB 11311" because it is unclear what characteristics are encompassed in this limitation. Applicants traverse.

Applicants believe that it is clear from the specification that "the characteristics of HB 11311" refers to the specific immunological reactivity exhibited by the anti-idiotypic antibodies produced from the monoclonal antibody that has been assigned the ATCC accession number HB 11311. See, *e.g.*, page 26, lines 19-25.

(c) The Examiner states that claims 9 and 14 are vague and indefinite in the recitation "multiple antigen peptide," because it is unclear what is encompassed in this limitation. Applicants traverse.

Applicants assert that "multiple antigen peptide" is adequately described in the specification as macromolecules that are comprised of multiple peptides attached to an amino acid scaffold that provides a high density of desired peptide epitopes on the surface of the macromolecule. See, *e.g.*, page 20 lines 14-17. Applicants believe that this description would be meaningful to one of skill in the art as of the filing date of the application.

(d) The Examiner states that claim 2 is vague and indefinite in the recitation "DE_GLF" because it is unclear what "_" represents. Applicants traverse.

Applicants assert that the specification clearly shows that "_" in the context of a peptide sequence represents a position in the sequence at which any amino acid residue can be included. See, *e.g.*, page 9, lines 3-5 and Figure 5.

(e) The Examiner states that claim 6 is vague in the recitation "tail" because it is unclear what it contains or what the composition is. Applicants traverse.

The application makes clear that the recitation "tail" refers to cyclic peptide mimics as recited in the specification on page 19, lines 23-27.

(f) The Examiner states that claims 4-10 and 15 are indefinite because they depend directly and indirectly from a base claim that is vague and indefinite.

As discussed above, applicants believe they have clarified the base claims from which claims 4-10 and 15 depend, thereby obviating the rejection.

For all the above reasons outlined in (a) through (f), applicants respectfully request that the Examiner withdraw the 35 U.S.C. §112, second paragraph rejections.

35 U.S.C. § 102

The Examiner has rejected claims 1, 3 and 9-15 under 35 U.S.C. § 102(e) as being anticipated by the '839 patent. Specifically, the Examiner states that the '839 patent disclosed fragments of anti-idiotypic antibodies and antibodies themselves which immunospecifically bind to antibodies that recognize oligosaccharide epitopes of *N. gonorrhoeae*. The Examiner contends that it is inherent from the teachings of the '839

patent that the binding fragments disclosed in the prior art intrinsically serve as peptide mimics. Applicants traverse.

Applicants disagree with the Examiner's assertion that it is inherent from the '839 patent that the binding fragments disclosed would intrinsically serve as peptide mimics.

MPEP 2131 states that "[t]o anticipate a claim, the reference must teach every element of the claim." As discussed above, applicants assert that the '839 patent does not teach or suggest peptide mimics of gonococcal epitopes. Nor does the '839 patent specify any peptide sequences that correspond to those taught in the instant invention. (See Rice Declaration ¶¶ 8-12). Applicants therefore assert that the '839 patent does not contain each element of claims 1, 3 and 9-15 of the instant application. Thus, claims 1, 3 and 9-15 are not anticipated under 35 U.S.C. § 102(b) by the '839 patent. Accordingly, applicants respectfully request that Examiner withdraw this 102(e) rejection.

The Examiner has rejected claims 1, 3 and 9-15 under 35 U.S.C. § 102(e) or 102(a) as being anticipated by the '067 patent. Specifically, the Examiner states that. the '067 patent disclosed fragments of anti-idiotypic antibodies and antibodies themselves which immunospecifically bind to antibodies that recognize oligosaccharide epitopes of *N. gonorrhoeae*. The Examiner contends that it is inherent from the teachings of the '067 patent that the binding fragments disclosed in the prior art intrinsically serve as peptide mimics. Applicants traverse.

The '067 patent is a continuation application of the '784 patent and therefore discloses the same binding fragments. Applicants reiterate, as discussed above

regarding obviousness-type double patenting, that the '067 patent does not teach or suggest the instantly claimed peptide mimics of gonococcal epitopes, nor does the '067 patent specify any peptide sequences that correspond to those taught in the instant invention.

For the above reasons, the '067 patent does not contain each and every element of claims 1, 3 and 9-15 of the instant application. These claims are therefore not anticipated under 35 U.S.C. § 102(e) or 102(a) by the '067 patent. Accordingly, applicants respectfully request that Examiner withdraw this 102(e) or (a) rejection.

The Examiner has rejected claims 1, 3 and 9-15 under 35 U.S.C. § 102(b) as being anticipated by the '784 patent. Specifically, the Examiner states that the '784 patent disclosed fragments of anti-idiotypic antibodies and antibodies themselves which immunospecifically bind to antibodies that recognize oligosaccharide epitopes of *N. gonorrhoeae*. The Examiner contends it is inherent from the teachings of the '784 patent that the binding fragments disclosed in the prior art intrinsically serve as peptide mimics, with the whole anti-idiotypic antibody comprising the binding fragment viewed as the multiple antigen peptide. Applicants traverse.

For the reasons discussed above, the claimed peptide mimics of the instant inventions and the antibody fragments of the '784 patent are not the same. Moreover, an anti-idiotypic antibody cannot be equated with a multiple antigen peptide as described in applicant's invention. One of skill in the art reading the instant specification would recognize the distinction between these two very different molecules.

Therefore, the '784 patent does not contain every element of claims 1, 3 and 9-15 of the instant application. These claims are therefore not anticipated under 35

U.S.C. § 102(b) by the '784 patent. Accordingly, applicants respectfully request that Examiner withdraw this 102(b) rejection.

The Examiner has rejected claims 1, 3 and 9-15 under 35 U.S.C. § 102(a) as being anticipated by Ngampasutadol et al. (In: Abstracts of the Eleventh International Pathogenic Neisseria Conference, (Ed) Nassif X et al. Nice, France, 1998, p. 159).

Applicants submit an executed Declaration under 37 U.S.C. § 1.131 ("131 Declaration") showing that the present invention was carried out before the publication date of Ngampasutadol et al. Applicants believe that this 131 Declaration obviates the 102 (a) rejection based on Ngampasutadol et al. (See ¶¶ 1-8 of the 131 Declaration).

Applicants have also appended hereto as Exhibit A, a copy of the cover, copyright and title page of the Ngampasutadol et al. abstract book, which indicates a publication date of November, 1998.

35 U.S.C. § 103

The Examiner has rejected claims 1-15 under 35 U.S.C. § 103(a) as being unpatentable by Ngampasutadol et al. (In: Abstracts of the Eleventh International Pathogenic Neisseria Conference, (Ed) Nassif X et al. Nice, France, 1998, p. 159) and Tam (In: Peptide Antigens: A Practical Approach. (Ed) Wisdom G.B. IRL Press, Oxford University Press, New York, 1993, pp. 83-90). Specifically, the Examiner states that it would have been obvious to one of ordinary skill in the art at the time of the invention was made to add the cysteine residues disclosed in Tam at each terminus of the DE_GLF peptide mimic, disclosed in Ngampasutadol et al., and/or modify the peptide mimic as a multiple antigen peptide with a built-in adjuvant as taught by Tam to the produce the instant invention with a reasonable expectation of success. The Examiner further states

that one of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of protecting the DE_GLF peptide mimic from modification and to advantageously effect polymerization via disulfide formation as taught by Tam and or modify the DE_GLF peptide mimic as a multiple antigen peptide with a built-in adjuvant for the purpose of advantageously providing a very high density of the peptide mimic as taught by Tam. Applicants traverse.

MPEP 2141.01 states "[a]n obviousness rejection based on a publication which would be applied under 102(a) if it anticipated the claims can be overcome by swearing behind the publication date of the reference by filing an affidavit or declaration under 37 CFR 1.131." Applicants believe that by submitting an executed Declaration under 37 U.S.C. § 1.131 showing that the inventors carried out the present invention before the publication date of Ngampasutadol et al., that Ngampasutadol et al. is no longer to be considered prior art under 35 U.S.C. § 102(a). Since Ngampasutadol et al. is no longer prior art under § 102(a), applicants believe that the 35 U.S.C. § 103(a) rejection may properly be withdrawn.

In item 20), the Examiner has rejected claims 1 and 3-15 in what appears to be a § 103 rejection, even though anticipation under § 102(b) is cited. Specifically, the Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the cysteine residues disclosed in Tam at each terminus of the peptide mimic, disclosed in the '784 patent, and/or modify the peptide mimic as a multiple antigen peptide with a built-in adjuvant as taught by Tam to produce the instant invention with a reasonable expectation of success. The Examiner further states that one of ordinary skill in the art would have been motivated to produce the

instant invention for the expected benefit of protecting the peptide mimic from modification and to advantageously effect polymerization via disulfide formation as taught by Tam and/or modify the peptide mimic as a multiple antigen peptide with a built-in adjuvant for the purpose of advantageously providing a very high density of the peptide mimic as taught by Tam. Applicants traverse.

Applicants respond under the assumption that this is a § 103 rejection of claims 1 and 3-15 in view of Tam and the '784 patent.

Contrary to the Examiner's assertions, neither the '784 patent nor Tam, separately or combined, teach or suggest adding cysteine residues at the terminus of peptide mimics directed to use as medicaments to treat *N. gonorrhoeae*. First, Tam is a general methods article that describes conjugating and polymerizing peptides by placing two cysteine residues at each terminus of a peptide to avoid the modification of epitopic sites. There is no suggestion in Tam to modify immunogenic peptides that mimic conserved gonococcal epitopes. Second, the '784 patent, as discussed above, relates to anti-idiotypic antibodies and fragments thereof useful in the methods and compositions for the prophylaxis of *N. gonorrhoeae* infections. The use of peptide mimics in the instant invention represent a new approach to overcome the limitations of anti-idiotypic antibodies as immunogens for *N. gonorrhoeae* infections. Thus, as discussed above, applicants believe that the subject matter claimed in the instant invention would not have been obvious in view of the '784 patent.

Specifically, the instant invention claims peptide mimics of at least 4 and less than 50 amino acids in length (See specification, *e.g.*, page 12, lines 1-6). In contrast, the '784 patent relates to anti-idiotype antibodies and fragments thereof wherein

the fragments are defined as Fab fragments, Fab' fragments, $F(ab')_2$ fragments, F(v), fragments comprised of one or more complementarity determining region(s) (CDR), heavy chain monomers or dimers, light chain monomers or dimers, dimers consisting of one heavy and one light chain, and the like. See, *e.g.* column 5, lines 30-37 of the specification of the '784 patent. One of ordinary skill in the art would have known that these fragments typically have at least 50 amino acid residues. There is no suggestion in the '784 patent to use the peptide mimics of the instant invention nor any suggestion to add cysteine residues at the terminus of peptide mimics for preventing or treating *N. gonorrhoeae* infection, nor would one of skill in the art have a reasonable expectation of success in doing so based on the '784 disclosure.

Applicants disagree with the Examiner's assertions that one of skill in the art would have been motivated to add cysteine residues at the termini of peptide mimics directed to use as medicaments to treat *N. gonorrhoeae* in view of the '784 patent and Tam. There is no motivation to combine these references because , as discussed above, the '784 patent and Tam nowhere teach or suggest peptide mimics or the use of peptide mimics in the production of medicaments for the prevention and treatment of gonococcal infection. Therefore, there would have been no motivation in the art to add cysteine residues at the termini of the peptide mimics for treating *N. gonorrhoeae* infection.

Similarly, as of the filing date of the instant invention, there was no reasonable expectation to be derived from the '784 patent and Tam that adding cysteine residues to the termini of peptide mimics would successfully prevent or treat *N. gonorrhoeae* infection because the '784 patent and Tam do not, alone or together, provide any instruction in this regard.

For the above reasons, applicants assert that claims 1 and 3-15 are not obvious under 35 U.S.C. § 103(a) in view of Rice et al. ('784 patent) and Tam. Accordingly, applicants respectfully request that Examiner withdraw the 103(a) rejection.

CONCLUSION

In view of the foregoing remarks, applicants request that the Examiner favorably reconsider this application and allow the claims pending herein. If the Examiner believes that a telephone conference would expedite allowance of this application, she is invited to telephone the undersigned at any time.

Respectfully submitted,

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Attachments
Exhibit A

Figure 2

PEP1	IPVL**DE**N**GLF**AP	[SEQ ID NO 1]
PEP2	WGLDY**E**R**G**N**Y**EE	[SEQ ID NO 2]
PEP3	DALAV**D**QM**G**R**F**G	[SEQ ID NO 3]
PEP4	VLVG**E**K**GLF**EGG	[SEQ ID NO 4]
PEP5	EALVL**D**TN**GL**MS	[SEQ ID NO 5]
PEP6	ADRTQ**GL**GWGAS	[SEQ ID NO 6]
PEP7	EEVGSILY**GL**GG	[SEQ ID NO 7]
CONSENSUS	**DE-GLF**	[SEQ ID NO 8]

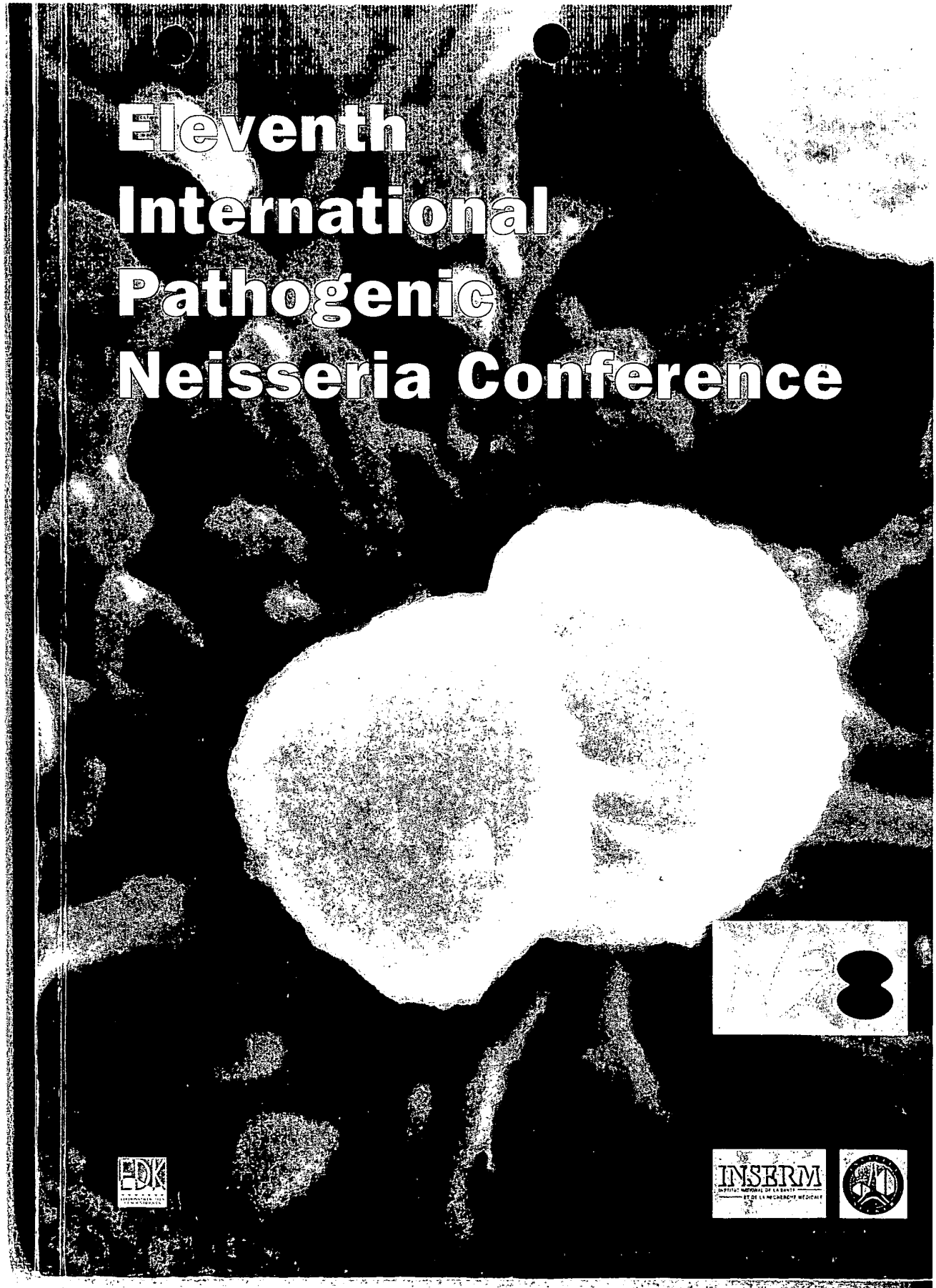
Annotated Sheet Showing Changes

Figure 2

PEP1	IPVL**DE**N**GLF**AP	[SEQ ID NO 1]
PEP2	WGLDY**E**R**G**N**Y**EE	[SEQ ID NO 2]
PEP3	DALAV**D**QM**G**R**F**G	[SEQ ID NO 3]
PEP4	VLVG**E**K**GLF**EGG	[SEQ ID NO 4]
PEP5	EALVL**D**TN**GL**MS	[SEQ ID NO 5]
PEP6	ADRTQ**GL**GWGAS	[SEQ ID NO 6]
PEP7	EEVGSILY**GL**GG	[SEQ ID NO 7]
CONSENSUS	**DE-GLF**	[SEQ ID NO 8]

Seq. Id. Nos. added

Exhibit A



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